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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,848	06/27/2003	Brian Leyland-Jones	3287.1005-000	4832

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,848	LEYLAND-JONES, BRIAN	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 25, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-124* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-42, 90-92 and 117-120, drawn to methods for identifying phenotypic determinants, classified in class 435/973, for example.

II. Claims 43-50 and 61-69, drawn to methods for using phenotypic determinants, classified in class 424/9.2, for example.

III. Claims 51-60 and 93, drawn to a system, classified in class 435/288.4, for example.

IV. Claims 70-89, drawn to methods for screening individuals, classified in class 436/811, for example.

V. Claims 94-96, drawn to a compound, classified in class 436/93, for example.

VI. Claims 97-116 and 121-124, drawn to immunogens, uses thereof, antigen binding fragments thereof, kits, and hybridoma cell lines, classified in class 435/70.21, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and IV are independent and patentably distinct from each other. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. For example, Invention I requires the step of detecting metabolites, which is not required in Inventions II and IV. Invention II requires the step of determining a safe dose of anticoagulant agent, which is not required in Inventions I and IV. Invention IV requires the step of selecting individuals with a particular phenotype, which is not required in Inventions I and II.

Inventions III and V are independent and patentably distinct from each other because Inventions III and V have different functions. For example, Invention III requires a means for detecting metabolites, which is

not required in Invention V. Invention V requires a specific heterocyclic compound, which is not required in Invention III.

Inventions III and VI are independent and patentably distinct from each other because Inventions III and VI have different functions. For example, Invention III requires a means for detecting metabolites, which is not required in Invention VI. Invention VI requires a specific heterocyclic compound, which is not required in Invention III.

Inventions V and VI are related as subcombination and combination, respectively. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a pharmaceutically acceptable carrier has separate patentable utility as a biodegradable implant, for example. The subcombination has separate utility as a fluorescent label, for example.

Inventions III and (I, II or IV) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention III can be used in a materially different process, such a process for screening libraries of organic compounds.

Inventions (V or VI) and (I, II or IV) are related as products and processes of use. The products of Inventions V or VI can be used in a materially different process, such a process for labeling and imaging intracellular targets.

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. Select ONE anticoagulant agent from:

    a. b2 adrenoreceptor antagonists;
    b. neuropeptide V2 antagonist;
    c. prostacyclin analogs;
    d. thromboxane synthase inhibitors;
    e. calcium agonists;
    f. coumarin derivatives;
    g. elastase inhibitors;
    h. NSAI thrombin inhibors;
    i. lipoxygenase inhibitors;
    j. Factor VIIa inhibitors;
    k. Factor Xa inhibitors;
    l. phosphodiesterase III inhibitors;
    m. heparins;
    n. fibrinogen glucoprotein Iib/IIIa antagonists; OR
    o. warfarin.

2. Select ONE affinity complexation agent from:

    a. antibody, monoclonal antibody, polyclonal antibody;
    b. molecular imprinted polymer;
    c. aptamer;
    d. receptor; OR
    e. anticalin.

3. Select ONE detection method from:

    a. immunoassay, ELISA;
    b. microarray formatted immunoassay, microarray formatted ELISA;
    c. Dipstick;
    d. RAMP;
    e. light-emitting immunoassay;
    f. biosensor;
    g. immunosensor;
    h. electrochemical sensor;
    i. optical sensor;
    j. microgravimetric sensor;
    k. QCM;
    l. qualitative detection instrument;
    m. CCD imager; OR
    n. densitometer.

4. Select ONE drug metabolizing enzyme from:

a. CYP2C9;
b. NAT-1;
c. NAT-2;
d. CYP1A2;
e. CYP2D6;
f. CYP2A6;
g. CYP2E1;
h. CYP3A4;
i. CYP2C19;
j. UGTs;
k. GSTs; OR
l. STs.

5. Select ONE determinant from:

a. body surface area;
b. hepatic enzyme levels; OR
c. pretreatment renal function.

Applicant is required under 35 U.S.C. 121 to elect one species from each of 1, 2, 3, 4 and 5, above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 43, 47, 51, 61, 70, 74 and 83 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a complete reply to this requirement must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Because the aforementioned Inventions and species are distinct for the reasons given above and the searches required for each group are not coextensive, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/06/05